K113275

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510(k) Summary
[As required by 807.92(c)]

Date of issue: Jan 25, 2012

A. 510k Number

B. Applicant/Applicant
Company Name: BSR KOREA Corp.
Address: Migun Techno World 2 C-dong, 524, #533-1 Yongsan-dong, Yuseong-gu, Daejeon, KOREA.
Tel: 82-42-476-2977 Fax:82-42-476-2978
Contact person: Eileen Yang

C. Proprietary and Established Names:
WONJIN MULSAN Co., Ltd.
Address: 10B-7L 623-6 Namchon-dong, Namdong-gu Incheon, Korea

D. Regulatory information
1. Classification Name: Massager, Powered Inflatable Tube
2. Common/Usual Name: Powered inflatable Tube Massager
3. Proprietary Name: Compressible Limb Therapy System (Power-Q1000 Premium)
4. Classification /Product Code: Class 2, IRP(21 CFR 890.5650)

E. Intended Use
Power-Q1000 Premium is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

F. Device Description
Power –Q1000 Premium is used with four chamber garments for full leg, and period has its own variable duration pressure, cycle time and gradient setting. Power unit features visual operation statusand fault indicators.

G. Technological characteristics

Name	Power-Q1000 Premium
Pressure (mmHg)	0~240mmHg
Mode	A, B, C, D(D1, D2, D3, D4), E selection. (The initial set : Mode A)
Interval	Interval : 0, 5, 10, 15, 20, 25, 30 sec, selection. (The initial set : 0sec)
Time(min)	Time(min) : 5~99min, selection. (The initial set : 15min)
Pressure Time	Pressure : 0~240mmHg, selection (The initial set : 200mmHg) 0~240 : A, B, D(D1, D2, D3, D4) Mode 0~130 : C, E Mode

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H. Substantial Equivalence Information

1. Predicate Device

-510(k) Number: 100656

–Name: Compressible Limb Therapy system(WHF-324 POWER-Q1000 PLUS)

-Classification: 2

2. Comparison with predicate

Model Name	Power Q1000 Premium	WHF-324 (POWER-Q1000) (predicate device)
510(k) number	None yet	k100656
Classification	Class Ⅱ Device/ IRP (21 CFR 890. 5650)	Class Ⅱ Device/ IRP (21 CFR 890. 5650)
Intended use	The device is indicated for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, edema following trauma and sport injures, Postimmobilization edema, Venous insufficiencies, Lymphedema.	The device is indicated for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, edema following trauma and sport injures, Postimmobilization edema, Venous insufficiencies, Lymphedema.
Description	Power Q1000 Premium is a pneumatic pressure treatment system that repeats expansion of sleeves to help blood circulation and prevent blood clots or clogs.	Power Q1000 PLUS is a pneumatic pressure treatment system that repeats expansion of sleeves to help blood circulation and prevent blood clots or clogs
Standard	EN ISO14971 EN60601-1 EN60601-2-10 EN60601-1-2	EN ISO14971 EN60601-1 EN60601-2-10 EN60601-1-2
Indications	Primary lymphedema, Edema following trauma and sport injuires, postimmobilization edema, Venous insufficiencies, Lymphedema.	Primary lymphedema, Edema following trauma and sport injuires, postimmobilization edema, Venous insufficiencies, Lymphedema.
Contraindications	Acute pulmonary edema Acute throubophlebitis Acute congestive cardiac failure Acute infections, Deep vein thrombosis Episodes of pulmonary embolism Wounds, lesions, or turmors at or in the vicinity of application	Acute pulmonary edema Acute throubophlebitis Acute congestive cardiac failure Acute infections, Deep vein thrombosis Episodes of pulmonary embolism Wounds, lesions, or turmors at or in the vicinity of application

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	Where increased venous and lymphatic return is undesirable, Bone fractures or dislocation at or in the vicinity of application	Where increased venous and lymphatic return is undesirable, Bone fractures or dislocation at or in the vicinity of application
Mode of Compression	Sequential	Sequential
Power source		Electricity Supply: 220-240V 50/60HZ
Therapy Time	0~99 minutes	0-30 minutes
Maximum and Minimum Pressure	0-240mm Hg	0-300mm Hg
Number of Chambers	4 Chambers for each unit	4 Chambers for each unit
Compression Applicator Garments Sleeve material	Nylon	Nylon

J. Performance characteristics

The Model Power-Q1000 Premium has tested and meets the requirements of the following standard.

-EN60601-1, Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988/A1:91/A2:9s)

-EN60601-2-10, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

-EN60601-1-2, Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility

K. Conclusion

Compressible Limb Therapy System WHF-324 (POWER-Q1000 PLUS)) has substantial equivalent intended use as the-market-cleared WHF-314(POWER-Q1000) and has substantial equivalent technological and performance characteristics. After analyzing laboratory testing to applicable standards, it is the conclusion of WONJIN MULSAN Co., Ltd. that Compressible Limb Therapy System (WHF-324 (POWER-Q10 PLUS)) is as safe and effective as the predicate devices, has few technological differences, but there are no new indications for use and without raising any new safety and/or effectiveness concerns. Consequently, it is clear that it substantially equivalent to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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℅ BSR Korea
Ms. Eileen Yang
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533-1 Yongsan-Dongyuseong-Gu
Daejeon
Republic of Korea KS

Re: K113275
Trade/Device Name: Compressible Limb Therapy System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: February 14, 2012
Received: February 14, 2012

Dear Ms. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Compressible Limb Therapy System Model No. POWER-Q1000 Premium

Indications for Use:

The device is indicated for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, edema following trauma and sport injures, Postimmobilization edema, Venous insufficiencies, Lymphedema.

Prescription Use __x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113275